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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/472,662 12/27/99 HAMMERMAN

M A-68752-1/RF

EXAMINER

HM22/0605

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ART UNIT

PAPER NUMBER

1653

DATE MAILED:

06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/472,662

Applicant(s)
Hammerman

Examiner
F. MOEZIE

Art Unit
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/7/00 and 4/17/01.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-12 is/are pending in the application.
- 4a) Of the above, claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 3-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 (3 pages) 20) ☐ Other:

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DETAILED ACTION

STATUS OF CLAIMS

Claims 3-10, drawn to embryonic metanephric tissue which has been pretreated and a method for the treatment of metanephric tissue, are pending prosecution in this Office action.

Election of Specie - vascular endothelial growth factor is acknowledged.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. The terms "pretreated" and "enhanced renal development or function as compared to metanephric tissue which has not been pretreated" in claim 3 are relative terms which render the claim indefinite. The above terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The prefix "pre" does not indicate the time frame (minutes, hours, or longer). Moreover, it is not clear as to the "enhanced development and function" what has developed and which function is "enhanced" and by how much.

3. Claim 4 is an indefinite and improper claim as it depends from claim 4.

In claim 5, the term "at a suitable stage" render the claims indefinite as to what stage is called suitable.

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Claims 4-10 are indefinite because then encompass an improper Markush grouping, as they lack a common core.. Inclusion of vitamin A as a growth factor is improper.

REJECTION - 35 U.S.C. 102 (e)/103 (a)

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

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made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-8 are rejected under 35 U.S.C. 102(e or b) as being anticipated by Zsebo et al in US Patent No. 6,204,363, filed 10 April 1991 or earlier or EP 0 853 842, published 7/22/98.

The reference teaches that growth enhancement of metanephric kidney tubules occur by treating said tissue with a composition comprising SCF (a growth factor, col. 3, line 63 and col. 12, lines 34-39 and lines 66+), and/or other growth factors, wherein the growth factor is IGF-I or LIF. See, col. 12, line 66 to col. 13, line 45. The reference also teaches pretreating the donor or the recipient of the transplant with a growth factor. See col. 14, lines 8-21 and col. 79, lines 20-67. The in-vitro survival and proliferation of stem cells is taught at col. 85, Example 26 to col. 86, line 33. See, the entire document.

The EP document teaches: "Embryonic metanephric tissue which has been obtained from a donor at a suitable stage of embryonic development is provided for use in a method of increasing the functioning nephron mass of a recipient by implanting said metanephric tissue next to the recipient's omentum or under the renal capsule of the recipient's kidney under conditions that allow the metanephric tissue to vascularize and develop to form urine" abstract. Further, the reference teaches that the administration of growth factors at the time of and subsequent to implantation of the donor metanephric tissue can facilitate development and function of the tissue. VEGF is the growth factor for use because it promotes angiogenesis (page 5, lines 9-15). The

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reference also discloses and claims the use of IGF-I for growth and development of embryonic metanephric tissue in claim 27. See the entire document.

One of ordinary skill in the art at the time the invention was made would have immediately envisaged the claimed subject matter in view of the teachings of the prior art.

RESPONSE TO APPLICANT

The response to Restriction Requirement and Election of Species filed April 17, 2001, paper no. 6, has been considered.

Claims 1 and 2 have been canceled. Claims 3-10, drawn to a method, have been elected. Claims 11 and 12, drawn to a composition, have been subject to a rejoinder upon finding allowable method claims, as set forth earlier in paper no. 5, mailed 3/5/01, at page 3, second paragraph.

STATUS OF CLAIMS

No claim is allowed.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Mr. LOW (SPE) at 308-2923.

F.T. MOEZIE
PRIMARY EXAMINER
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